BILL NUMBER: SB 1307 AS PROPOSED TO BE AMENDED

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INTRODUCED BY Senator Ridley-Thomas

FEBRUARY 20, 2008

An act to amend Sections 4034, ~~and~~ 4163 ***and 4314*** of, to add Sections 4034.1, 4163.2, and 4163.3 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug ***from the point it leaves the accredited distribution chain***, ~~from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies,~~ until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system~~, ensuring compatibility throughout all stages of distribution~~.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision ~~(i)~~ ***(j)***.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from ***the point it leaves the accredited distribution chain*** ~~its initial manufacture~~ through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or

immediate container" of a dangerous drug shall be the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug, ***that has left the accredited distribution chain,*** to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) (A) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(B) The exemption in this paragraph shall expire and be inoperative on January 1, 2012, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2013. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(3) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date ~~for manufacturers~~ set forth in subdivision ~~(k)~~ ***(l)*** of Section 4034 ~~or Section 4163.5~~, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(4) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(5) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance that meets medical purity standards and has application in a medical environment, including, but not limited to, oxygen and nitrous oxide.

(6) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(7) The sale, transfer or trade of a dangerous drug through the accredited distribution chain. For purposes of this section, "accredited distribution chain" means a chain of custody for a dangerous drug that goes by drop shipment or is directly sold, traded or transferred from either: (a) a manufacturer of the dangerous drug; (b) a manufacturer's co-licensee; (c) a manufacturer's wholesaler; (d) a manufacturer's exclusive distributor to: a chain pharmacy wholesaler, pharmacy, hospital, clinic or other designated persons authorized by law to dispense or administer the drug to a patient; or either (e)(1) a distributor or wholesaler that is accredited by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributors program or (2) other standards adopted by the Board developed pursuant to subdivision (h). For purposes of this section "chain pharmacy wholesaler" means a physical location for drugs that acts as a central warehouse and performs intracompany sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(h) ***The board shall develop guidelines for the purpose of accrediting distributors and wholesalers who are not accredited by the National Board of Pharmacy. These guidelines shall include provisions that provide assurance of security to the supply chain and patient protection. The guidelines shall be developed by regulation on or before January 1, 2010. The Board shall consult with the Healthcare Distribution Management Association and representatives from the secondary wholesalers.***

(i) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

~~(i)~~ ***(j)*** "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point ~~of manufacture~~ ***the drug leaves the accredited distribution chain***, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

~~(j)~~ ***(k)*** The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

~~(k)~~ ***(l)*** This section shall become operative on January 1, 2011.

However, the board may extend the date for compliance with this section and Section 4163 in accordance with Section 4163.5.

(m) The Board shall adopt regulations no later than January 1, 2010, setting forth the manner and means by which the prescription drugs, subject to the pedigree requirements are to be identified, validated and authenticated. The method of tracking and tracing the dangerous drugs shall utilize a standardized numerical identifier to be applied to the drug container at the point drug leaves the accredited distribution chain.

(n) The board shall establish by regulation the structure for an audit system that provides periodic auditing of the distribution of dangerous drugs within the state.

(1) All invoices and packing slips in the Accredited Chain of Distribution shall be by lot number corresponding to lot received.

(2) If (a) is not met, then the Board may impose penalties pursuant to Section 4314.

SEC. 2. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. Notwithstanding anything to the contrary in Section 4034 or 4163, if federal standards are developed pursuant to Section 505D of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355e) regarding the identification, validation, authentication, tracking, and tracing of prescription drugs, and with respect to a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repacking at the package or pallet level, ***sections 4034 and 4163 shall be deemed preempted by the federal standard upon the effective date of the federal standard, and*** the board shall immediately issue emergency regulations or take other action within 30 days to require use of the federally identified standardized numerical identifier as the unique identification number otherwise required by subdivision ~~(i)~~ ***(j)*** of Section 4034. In addition, if the federal standards developed pursuant to the above-referenced section of the federal act include a specification of standardized data elements of a pedigree record, those data elements shall be automatically substituted by the board for those otherwise required by subdivision***s*** (b)***- (h)*** of Section 4034. Notwithstanding subdivision ~~(k)~~ ***(l)*** of Section 4034, the requirements of this section with respect to the use of standardized numerical identifiers and specification of standarized data elements shall be in effect immediately upon the board's action to implement this section.

SEC. 3. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section ~~4163.5~~ ***4034***, commencing on January 1, 2012, a wholesaler may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree ***to a non-accredited person***.

(d) Except as otherwise provided in Section ~~4163.5~~ ***4034***, commencing on January 1, 2012, a wholesaler may not acquire a dangerous drug without receiving a pedigree ***from a non-accredited person***.

(e) Except as otherwise provided in Section ~~4163.5~~ ***4034***, commencing on July 1, 2012, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree ***to a non-accredited person***.

(f) Except as otherwise provided in Section ~~4163.5~~ ***4034***, commencing on July 1, 2012, a pharmacy may not acquire a dangerous drug without receiving a pedigree ***from a non-accredited person***.

SEC. 4. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory number and batch number and the dates of manufacture for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations.

(b) (1) For up to 18 months following the operative date of the pedigree requirements, any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its National Drug Code Directory number and batch number and date of manufacture, met the requirements of subdivision (a) and the written declaration prepared pursuant to subdivision (a) shall be attached to this written declaration.

(3) Both the transferring and receiving parties shall retain for a period of three years and make available for inspection by the board a copy of each written declaration.

(4) The board may, by regulation, further specify the requirements and procedures for these transfers and the necessary documentation.

(5) The board may, by regulation, further extend beyond 18 months the period for transfers of nonpedigreed drugs, either for all drugs or for specified categories or subcategories of drugs.

SEC. 5. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the ***non-accredited*** distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic

pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, the board shall, by regulation, define the circumstances under which the board deems it appropriate for participants in the ***non-accredited*** distribution chain to infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

SEC. 6. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 7. Section 4163.5 is added to the Business and Professions Code , to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1***) Technological innovations have the potential to provide significant benefits for consumers by improving communications between doctors and pharmacists; allowing accurate transfer of prescriptions between providers; and increasing the portability of personal health records for diagnosis and treatment.***

(2) ***The State Board of Pharmacy, in conjunction with the relevant stakeholder community including, but not limited to, consumer protection advocates, pharmaceutical manufacturers, health care providers, distributors, health facilities and pharmacists, shall work to assist the state in implementing electronic prescribing authority by 2012.***

(3) Public access to a safe, effective and reliable supply of beneficial drugs at reasonable costs help to extend and improve the quality of life of our state's citizens. ~~The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.~~

(3) ~~At the same time, it is recognized that the~~ ***The*** process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, pharmacies, and other supply chain participants~~. The Legislature seeks to ensure continued availability of prescription drugs in California while drug manufacturers implement these requirements.~~ ***and its effectiveness will be compromised without a national standard.***

(4) The federal government is strongly encouraged to develop a national standard for the tracking and tracing of drugs that will target any deficiencies in the supply chain without needlessly increasing the costs or limiting access of drugs to the public.

(b) ***The Board shall annually post on their website a report on:***

(1) Any case of counterfeit drugs in California confirmed by a state or federal agency.

(2) The source of the counterfeit drug.

(3) The location the counterfeit drug entered the supply chain.

(4) Corrective or enforcement actions taken in response.

~~On or before January 1, 2010, each manufacturer of a dangerous drug to be distributed in California shall designate drugs representing a minimum of 20 percent of the drugs, generic or single source, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the state's serialized pedigree requirement set forth in Sections 4034 and 4163. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.~~

~~(c) On or before January 1, 2011, each manufacturer shall designate a minimum of an additional 30 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2012. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.~~

~~(d) On or before January 1, 2012, each manufacturer shall designate a minimum of an additional 50 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2013. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.~~

~~(e) All new dangerous drugs that are approved for sale on or after January 1, 2011, shall be subject to the serialized electronic pedigree requirements set forth in Sections 4034 and 4163 when introduced on the market, and shall not be included in a manufacturer's yearly implementation quota.~~

~~(f) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.~~

Sec. 8. Section 4314 of the Business and Professions Code is amended to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to,

submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) ***Notwithstanding any other provision of law, for any knowing or intentional violation of Section 4034, the board may issue a citation containing a fine not to exceed $10,000 for each event.***

(e) Any entity that knowingly or intentionally fails to produce sufficient records required to demonstrate compliance with Section 4034 (n) shall be subject to a fine of up to $5,000 per saleable unit.

(f) Any entity that knowingly or intentionally provides the board with a fraudulent pedigree shall be subject to a fine of up to $5,000 per saleable unit.

(g) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.